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October 28, 2016

Patented Medicine Prices Review Board
(Rethinking the Guidelines)
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Servier Canada Inc. (Servier) would like to thank the Patented Medicine Prices Review Board (PMPRB) for the opportunity to comment on the *Guidelines Modernization Discussion Paper*, published on June 24th, 2016. This consultation document aims to obtain submissions from stakeholders and the public regarding possible reform of its Guidelines in order to modernize and simplify PMPRB's regulatory framework around patented drug pricing in Canada and remain relevant in a "dynamic and evolving pharmaceutical market". The *Discussion Paper* reveals a number of areas that may require changes to current Guidelines and Servier would like to provide feedback on a few of these areas.

Please note that as a member of Canada's Innovative Medicines Canada (IMC), Servier also supports, and is in agreement with, the response and position submitted by IMC to PMPRB on October 24, 2016, as part of this consultation.

Servier is a research-based organisation established in 140 countries and focused on further improving health and bringing better care to patients. With more than 20,000 employees worldwide, Servier is managed by a Foundation and reinvests 25% of its global turn-over in Research & Development (R&D). Established in Canada since 1978, Servier Canada is based in Laval (Québec) and employs more than 325 highly qualified individuals.

The Role and Mandate of the PMPRB

The PMPRB was established, pursuant to amendments to the *Patent Act* that came into force on December 7, 1987, with the following dual role:

- Regulatory – To ensure that the prices charged by patentees for patented medicines sold in Canada are not excessive; and
- Reporting – To report on pharmaceutical trends and on the research and development (R&D) spending by patentees.

In their *Discussion Paper*, PMPRB rightly notes the significant changes that arose in their operating environment since their creation in 1987, hence the reason for a possible reform and need for a revision of Guidelines.

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Affordability vs Excessiveness

Based on the *Discussion Paper*, PMPRB intends to expand its mandate to include affordability. This new concept seems to go far beyond PMPRB's role as established by Parliament, is outside of PMPRB's jurisdiction as set out by the Patent Act, and would require more than changes to the Guidelines, which is the purpose of the ongoing consultation. Introducing affordability to its mandate would also create duplication in the role of the provincial/territorial governments who already have the power and measures in place to evaluate affordability with respect to their budgets, programs, health care systems and/or economies. Moreover, the pan-Canadian Pharmaceutical Alliance (pCPA) was created to lower drug costs through collective negotiations, reduce duplication of negotiations, and improve access to new medicines. Servier believes that PMPRB's original mandate remains appropriate and relevant in the current Canadian pharmaceutical environment, and affordability should remain in the hands of budget holders who are accountable to their constituents and able to negotiate pricing based on their objectives and needs.

Research & Development

The second part of PMPRB's mandate is to report on pharmaceutical trends and on the R&D spending by patentees. The *Discussion Paper* refers to the relationship between price, Intellectual Property (IP) protection and R&D investments. To our knowledge, very few countries formally link investments, IP and pricing. Servier values that PMPRB's current jurisdiction allows for tracking of patented medicines and spending alongside investment in R&D by pharmaceutical companies. However, instead of simply reporting this information back to the population, it should be leveraged to encourage investment in health innovation in Canada by adopting economic development policies that would stimulate competitiveness and attractiveness toward investments.

The *Discussion Paper* states that R&D is declining in Canada. It fails to mention that the current R&D model for innovative pharmaceutical companies has evolved considerably (including the way organizations are now investing in Canada as a result of new business models) since PMPRB's creation while the methodology for determining R&D spending has essentially remained unchanged. Consequently, many of the indirect investments and contributions made by the pharmaceutical industry are not captured in the current calculation of R&D ratios made public in PMPRB's Annual Reports, thus not recognizing the significant improvement to Canadian investments for patented medicines. For instance, financial flows coming from a foreign entity outside Canada (such as a global pharmaceutical company head office) are not considered while still representing significant contribution to the Canadian economy.

Servier encourages a process for a regulatory agency such as PMPRB that would avoid duplication or overlap, and would accurately track and report on pharmaceutical trends and R&D, while creating a market place that encourages innovation and investments, and provides timely access to medicines for Canadians.

Differential vs Preferential Pricing

Innovation is key to ensuring that Canadian patients benefit from new and effective medicines, and live healthier and longer lives. In order to ensure that the most vulnerable Canadians (e.g., seniors, low-income population) have access to the medication they need, preferential pricing is provided to public payers through provincial government initiated rebates. Even though private drug plans do not have access to this preferential pricing, their distinct business model is capable and has the tools in place for assessing value, negotiating reimbursement terms and ensuring their own drug plan sustainability. Similar to the public drug plans, private drug plans can also negotiate with manufacturers in order to determine best value for their members (comprised largely of younger and healthier population), and do offer a multitude of formularies and plan designs not available in the public sector that are addressing cost issues and allows them to make profit. Servier believes that it could be counterproductive for a public agency such as the PMPRB to interfere in a business to business relationship.

Relevancy of the PMPRB within the Current Health Care System

Servier aims to provide the Canadian medical community and their patients the best possible therapeutic solutions through the discovery and development of new innovative therapies. Innovation is an investment in our society and in our economy. Servier agrees with IMC's belief that Guidelines to reduce pricing thresholds for patented medicines will not solve the problem of individuals facing affordability issues due to the lack of or insufficient drug coverage. The role and mandate of the PMPRB cannot be taken in isolation and Guidelines changes, if any, should be thought of as being part of a holistic system and not silo-based. An innovative collaboration between the federal, provincial and territorial governments, pharmaceutical industry and private payers would more likely improve timely and affordable access of innovative medicines to all Canadians and could specifically address the precise needs of subsets of the population that cannot afford new effective therapies.

In closing, Servier recommends that any changes to the Guidelines remain within the scope and mandate of the PMPRB, allow for sufficient time for dialogue and consultation as well as for potential grandfathering provisions to be developed accordingly.

Servier believes that providing access to innovative medicines allows Canadians to benefit from a world-class health care system. We appreciate the opportunity to provide feedback on the *Discussion Paper*, as an important stakeholder of this system. Should you have any questions, please feel free to contact me.

Yours sincerely,

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Chief Executive Officer
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